UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,127	04/19/2004	Mitchell Kyle	44564.004	2311

7590 10/05/2005

Intellectual Property Department
DEWITT ROSS & STEVENS, S.C.
Firstar Financial Centre
8000 Excelsior Drive Suite 401
Madison, WI 53717-1914

EXAMINER	
HENRY, MICHAEL C	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/827,127	KYLE, MITCHELL	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 08/10/05.

The amendment filed 08/10/05 affects the application, 10/827,127 as follows:

1. Claims 1-13 have been canceled. New claims 14-18 have been added. This leaves claims 14-18.

The responsive to applicants' arguments is contained herein below.

Claims 14-18 are pending in the application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 provides for "the use of of zinc oxide and sodium heparin admixed with non-medicinal carriers ....." but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. In addition, it should be noted that "the use of" is not a statutory class of invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 18 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saliba, Jr (US 4,879,282) in combination with Costello (US 5,874,094).

In claim 14, applicant claims "A composition for treating insect bites and stings, comprising a therapeutically effective amount of zinc oxide and sodium heparin admixed with pharmaceutically acceptable non-medicinal carriers selected from the group consisting of carboxymethylcellulose, glycerin, polysorbate and water, wherein said effective amount for zinc oxide is in the range of 1-20 mg/g and for sodium heparin is in the range of 100-300 USP units/g of said composition. Claim 15 is drawn to the composition according to claim 14, wherein said effective amount for zinc oxide is 5 mg/g and for sodium heparin is 160 USP units/g of said composition.

Saliba, Jr discloses a composition comprising an effective amount of sodium heparin which can be used for treating insect bites (see abstract and col. 7, lines 25-35).

Castello discloses that zinc oxide can be used to treat insect bites (see col. 4, lines 36-54).

The difference between applicant's claimed composition and the composition taught by Saliba, Jr is that applicant also uses a zinc oxide in their composition and a non-medicinal carrier. However, Castello discloses that zinc oxide can be used to treat insect bites, and the use of a non-medicinal carriers such as water in said composition is common in the art.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Saliba, Jr and Costello, to have prepared a composition comprising a combination of sodium heparin and zinc oxide to treat insect bites, since the combination of compounds that are used to treat the same diseases or condition are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated, in view of Saliba and Costello, to have prepare a composition comprising a combination of sodium heparin and zinc oxide to treat insect bites, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Saliba and costello, to treat insect bites based on type and/or severity of the insect bite. It should be noted that the use of specific amounts of sodium heparin and zinc oxide and depends factors such as severity and type of the insect bite treated.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saliba, Jr (US 4,879,282) in combination with Costello (US 5,874,094).

In claim 16, applicant claims "A method for treating insect bites and stings, comprising applying topically to the affected area an effective amount of zinc oxide and sodium heparin

admixed with pharmaceutically acceptable non-medicinal carriers selected from the group consisting of carboxymethylcellulose, glycerin, polysorbate and water, wherein said effective amount for zinc oxide is in the range of 1-20 mg/g and for sodium heparin is in the range of 100-300 USP units/g of the admixture. Claim 17 is drawn to the composition according to claim 16, wherein said effective amount for zinc oxide is 5 mg/g and for sodium heparin is 160 USP units/g of said admixture.

Saliba, Jr discloses a method of treating insect bites comprising administering topically an effective amount of sodium heparin (see abstract and col. 7, lines 25-35).

Castello discloses that zinc oxide can be used to treat insect bites (see col. 4, lines 36-54).

The difference between applicant's claimed method and the method taught by Saliba, Jr is that applicant also uses a zinc oxide in their composition and a non-medicinal carrier. However, Castello discloses that zinc oxide can be used to treat insect bites, and the use of a non-medicinal carriers such as water in said composition is common in the art.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Saliba, Jr and Costello, to have used the method of Saliba, Jr to treat insect bites with a composition comprising a combination of sodium heparin and zinc oxide, since the combination of compounds that are used to treat the same diseases or condition are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated, in view of Saliba, Jr and Costello, to have use the method of Saliba, Jr to treat insect bites with a composition comprising

a combination of sodium heparin and zinc oxide, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Saliba and costello, to treat insect bites based on type and/or severity of the insect bite. It should be noted that the use of specific amounts of sodium heparin and zinc oxide and depends factors such as severity and type of the insect bite treated.

Response to Arguments

The applicant arguments with respect to the references (Peshoff and Edwards et al.) are moot since applicant has canceled claims 1-13. Furthermore, the examiner has withdrawn the rejections of claims 1-13 made with the Peshoff and Edwards et al. references. This rejection was inadvertently included the prior final office action. The instant rejection is presently made over new claims 14-18 filed by applicant, with the application of new references (i.e., references different to that used in the non-final office) action and is made final since applicant's amendment has necessitated this new ground(s) of rejection.

Applicant's arguments with respect to claim 14-18 have been considered but are not found convincing.

The applicant argues that Saliba contends that heparin is effective when administered in almost any manner, to almost any ailment - and it is questionable whether one of ordinary skill would find this credible. However, without evidence to the contrary that refutes the effectiveness of heparin in treating the ailments disclosed by Saliba applicant's assumptions is discredited as lacking any factual basis. Furthermore, Saliba et al.'s patent is applied herein by the examiner with reference to the treatment of insect bites and not to any other aliment or condition. The applicant argues that when heparin is to be applied topically, it should be applied

at concentrations of 1,500 IU – 5,000 IU per ml (column 6 line 66 - column 7 line 35). and it should be accompanied by an acidic carrier (preferably with a PH of about 5.5); see column 7 lines 11-16. However, Saliba discloses that the application of heparin at concentrations of 1,500 IU – 5,000 IU per ml will be most efficacious (see col. 7, lines 25-35). Thus, this does not mean that concentrations outside this range will not be efficacious or effective although they may not be **most** efficacious. Moreover, the said concentration is in IU per ml and the amount or number of units to be used is not limited by Saliba since the amount of units used depends on the amount of ml(s) of the heparin used or applied, and Saliba does not require the use of any particular amount of ml(s) of heparin to be used. It should be noted at this juncture that applicant's claimed amounts of heparin is recited in units per gram (g) of the composition (e.g., 100-300 units/g, claim 1), thus the amount of units claimed by applicant in said method would also depends on the amount or number of grams (g) of the composition applied or used and thus the said amounts of units of heparin which can be used by Saliba and applicant can be equal. Furthermore, Saliba disclose that it is most efficacious to apply the heparin solution in a carrier having an acidic pH and particularly a pH of about 5.5 (column 7 lines 11-16). However, this does not imply that the carrier has to be at an acidic pH to be efficacious or effective, but only to be **most** efficacious. In addition, applicant composition is not limited to any particular pH and in fact applicant's claimed carrier (carboxymethylcellulose carrier) should have an acidic pH. The applicant argues that Costetlo discusses a topical cream using aloe vera as its active ingredient, along with vitamin E and zinc oxide (see abstract; column 3 lines 13-23). However, Costello discloses that zinc oxide is also an active ingredient or agent (see abstract and col. 4, lines 42 to 53). The applicant argues that Saliba suggest the use of heparin in a far greater amount than the

amount cited: 1,500-5,000 IU, as compared to the 100-300 USP (IU) claimed. On the contrary, Saliba discloses that the application of heparin at concentrations of 1,500 IU – 5,000 IU per ml will be most efficacious (see col. 7, lines 25-35). Thus, this does not mean that concentrations outside this range will not be efficacious or effective although they may not be **most** efficacious. Moreover, the said concentration is in IU per ml and the amount or number of units to be used is not limited by Saliba since the amount of units used depends on the amount of ml(s) of the heparin used or applied, and Saliba does not require the use of any particular amount of ml(s) of heparin to be used. It should be noted at this juncture that applicant's claimed amounts of heparin is recited in units per gram (g) of the composition (e.g., 100-300 units/g, claim 1), thus the amount of units claimed by applicant in said method would also depends on the amount or number of grams (g) of the composition applied or used and thus the said amounts of units of heparin which can be used by Saliba and applicant can be equal. The applicant argues that "

> Further, *Saliba* plainly suggests that one *not* add materials such as zinc oxide to heparin when used topically (as claimed): *Saliba* states that an acidic carrier should be used (with a preferred pH around 5.5), but topical zinc oxide has an approximately neutral (if not basic) pH, ranging between 6.95 and 7.37 – see the accompanying Intox entry (of which only pages 1 and 3 are provided, owing to the length of the entry). Thus, it is contrary to *Saliba*'s suggestions to add zinc oxide to heparin in the manner claimed.

However, Saliba does not plainly suggest or vaguely suggest that one cannot add materials such as zinc oxide to heparin when used topically (as claimed). Firstly, Saliba does not suggest that zinc oxide is a carrier nor that zinc oxide or other compounds cannot be combined or added to heparin. Furthermore, Saliba does not suggest that compounds with pH's that are not acidic cannot be combined with heparin. What Saliba suggests is that the heparin solution is most efficacious if an acidic carrier is used. In fact, the carrier and not the zinc oxide (which is not a

carrier) or other added compounds, will determine the final pH of the heparin solution. Also, applicant states that topical zinc oxide has an approximately neutral (if not basic) pH, ranging from between 6.95 and 7.37, this implies that topical zinc oxide is acidic at pH 6.95 (i.e., less than 7.00). Thus, Saliba does suggest that one cannot add materials such as zinc oxide to heparin when used topically. The applicant argues that Costello suggest a different wt% of zinc oxide than applicant. However, the use of different wt% of zinc oxide depends on factors like the severity of the insect bite, the type of subject treated and the other ingredients that comprises the composition such as heparin. The applicant argues that Saliba and Costello suggest that a topical mixture of heparin and aloe vera be used. However, Saliba and Costello also suggest that a topical mixture of heparin and zinc oxide be used, since zinc oxide (like aloe vera) is also a disclosed active ingredient. Applicant argues that Saliba suggest that any ingredient added to a topical composition should be acidic (unlike zinc oxide). However, Saliba do not suggest that any ingredient added to a topical composition should be acidic. As addressed above, Saliba suggest that the preferred carrier is an acidic (see above). Applicant argues that if one combine heparin and zinc oxide per Saliba and Costello, it would have vastly greater amounts of both heparin and zinc oxide than the combination claimed. However, the use of different amount of heparin and zinc oxide depends on factors like the severity of the insect bite, the type of subject treated. The applicant argues that claim 18 which recites the "use of" is a statutory method/process claim (see MPEP). However, the "use of" is not a statutory class of invention (see MPEP).

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

September 16, 2005.

SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1200